

Research Triangle Park Laboratories, Inc.

7201 ACC Blvd., Suite 104 Raleigh, NC 27617

919 510-0228 Telephone 919 510-0141 Fax

Web Site: www.rtp-labs.com



September 26, 2018

3B Medical 799 Overlook Drive Winter Haven, FL 33884

Attn: Alex Lucio, CEO

PROJECT: Ozone Testing RTP Labs ID: 18-079-2

The testing was conducted on the CPAP cleaning device received on September 7, 2018. We received a "SoClean 2 Go Model SC1300 S/N 1300SC052418128" device. The device was tested for ozone emissions to determine if it exceeded the Federal Regulation for medical devices 21 CFR 801.415 of 0.05 parts per million (ppm).

The testing was conducted using ASTM D5116 "Small Scale Chamber Determination of Volatile Organic Emissions from Indoor Materials/Products" using a 27-liter glass chamber. At the beginning of each test, an ozone Control sample was collected in the chamber to demonstrate that no ozone was in the chamber prior to turning on the device. The device was turned on and an ozone sample was collected and analyzed at 20 min time points for the "SoClean 2 Go" device. The "SoClean 2 Go" device automatically turned off after 14 min, and we modified our test procedure to test the ozone at 10 min. At the end of each test the device was removed and the chamber was purged with clean air to remove any residual ozone from the previous test.

	SoClean 2 Go Mask in bag w/filter	SoClean 2 Go Mask out of bag w/filter	SoClean 2 Go Mask out of bag Filter out of chamber	
Control	<0.05 ppm	<0.05 ppm	<0.05 ppm	
10 min	5.60 ppm	5.60 ppm	5.60 ppm	Exceeded
				Ozone Limit

If you have any questions, please give me a call at (919) 510-0228.

Sincerely,

Alston Sykes, Principal Chemist